28. Attached as Exhibit 27 to this declaration is a true and correct copy of a chain of emails dated from September 24 to September 27, 2010, along with three documents attached to the final email on September 27, 2010, as produced by FDA in February 2011.

29. Attached as Exhibit 28 to this declaration is a true and correct copy of the customs entry form for entry number 574-0250322-1, as produced by the ADC in December 2010.

30. Attached as Exhibit 29 to this declaration is a true and correct copy of a *Notice of FDA Action* dated September 29, 2010, as produced by the ADC in December 2010.

31. Attached as Exhibit 30 to this declaration is a true and correct copy of a timeline produced by the CDRC in January 2011.

32. Attached as Exhibit 31 to this declaration is a true and correct copy of a chain of emails dated between August 19 and 20, 2010, as produced by the CDRC in January 2011.

33. Attached as Exhibit 32 to this declaration is a true and correct copy of a chain of emails dated August 4, 2010, as produced by the CDRC in January 2011.

34. Attached as Exhibit 33 to this declaration is a true and correct copy of a chain of emails dated September 29, as produced by the CDRC in January 2011.

35. Attached as Exhibit 34 to this declaration is a true and correct copy of a chain of emails dated September 29, as produced by the CDRC in December 2010.

36. Attached as Exhibit 35 to this declaration is a true and correct copy of a pair of memoranda dated October 1, 2010, as produced by the CDRC in January 2011.

37. Attached as Exhibit 36 to this declaration is a true and correct copy of a sales agreement dated September 30, 2010, as produced by the TDC in January 2011.

38. Attached as Exhibit 37 to this declaration is a true and correct copy of the customs entry form for entry number 112-9247186-3, as produced by FDA in January 2011.

39. Attached as Exhibit 38 to this declaration is a true and correct copy of a document dated October 26, 2010, as produced by the TDC in January 2011.

40. Attached as Exhibit 39 to this declaration is a true and correct copy of the customs entry form for entry number 112-9938358-2, as produced by FDA in January 2011.

41. Attached as Exhibit 40 to this declaration is are three different copies of a chain of emails dated November 30, 2010, between FDA and CDRC officials. The first version is a true and correct copy of the version produced by FDA in January 2011. The second version is a true and correct copy of the version produced by FDA in February 2011. The third version is a true and correct copy of the version produced by the CDRC in February 2011.

42. Attached as Exhibit 41 to this declaration is a true and correct copy of an email sent by the CDRC to FDA on December 9, 2010, as produced by FDA in February 2011.

43. Attached as Exhibit 42 to this declaration is a true and correct copy of a letter from the CDRC to FDA on December 9, 2010, as produced by FDA in February 2011.

44. Attached as Exhibit 43 to this declaration is a true and correct copy of a chain of emails dated December 9, 2010, as produced by FDA in February 2011.

45. Attached as Exhibit 44 to this declaration is a true and correct copy of a chain of emails dated between December 9 and 20, 2010, as produced by FDA in February 2011.

46. Attached as Exhibit 45 to this declaration is a true and correct copy of a *Notice of FDA Action* dated January 6, 2010, as produced by FDA in January 2011.

47. Attached as Exhibit 46 to this declaration is a true and correct copy of a chain of emails between FDA and CDRC, dated between December 9, 2010, and January 7, 2011, as produced by FDA in February 2011.

48. Attached as Exhibit 47 to this declaration is a true and correct copy of a letter from FDA to CDRC dated January 7, 2011, as produced by FDA in January 2011.

49. Attached as Exhibit 48 to this declaration is a true and correct copy of a letter from the South Carolina Department of Corrections ("SCDC") to customs, as produced by FDA in February 2011.

50. Attached as Exhibit 49 to this declaration is a true and correct copy of the customs entry form for entry number 112-9673446-4, as produced by FDA in January 2011.

51. Attached as Exhibit 50 to this declaration is a true and correct copy of a *Notice of FDA Action* dated November 8, 2010, as produced by FDA in January 2011.

52. Attached as Exhibit 51 to this declaration is a true and correct copy of a collection of emails between FDA and the SCDC, dated from December 1, 2010, through January 5, 2010, as produced by FDA in January and February 2011.

53. Attached as Exhibit 52 to this declaration is a true and correct copy of a *Notice of FDA Action* dated January 6, 2011, as produced by FDA in January 2011.

54. Attached as Exhibit 53 to this declaration is a true and correct copy of a letter from FDA to the SCDC dated January 7, 2011, as produced by FDA in January 2011.

55. Attached as Exhibit 54 to this declaration is a true and correct copy of a chain of emails dated between September 24 and 27, 2010, as produced by FDA in February 2011.

56. Attached as Exhibit 55 to this declaration is a true and correct copy of a collection of documents related to Archimedes Pharma UK Limited and Link Pharmaceuticals Limited, which were obtained from the litigation file of *Blankenship v. Owens* in the United States District Court for the Northern District of Georgia, Atlanta Division.

57. Attached as Exhibit 56 to this declaration is a true and correct copy of the Dec. 19, 1980 citizen petition at issue in the *Heckler v. Chaney* litigation.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on March 21, 2011.

Washington, DC

Sean C. Griffin (DC Bar No. 499537)
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
(202) 736-8000

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Donald Edward BEATY, Daniel Wayne COOK, Eric J. KING, Brett Patrick PENSINGER, and Stephen Michael WEST, Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Kathleen SEBELIUS, and Margaret A. HAMBURG, M.D., Defendants.	**Civil Action No. 1:11-cv-00289 (RJL)** **ECF Case**

Exhibit 19 to the Declaration of Sean C. Griffin

DEPARTMENT OF THE TREASURY
UNITED STATES CUSTOMS SERVICE

Form Approved
OMB No. 1515-0069

ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

AIR EXPRESS

TEL: (b) (4) (b) (4)

19 CFR 142.3, 142.16, 142.22, 142.24

1. ARRIVAL DATE	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME	4. ENTRY NUMBER
091710		(b) (4)	112-8992979-0
5. PORT	**6. SINGLE TRANS. BOND**	**7. BROKER/IMPORTER FILE NUMBER**	
2095		(b) (4)	
	8. CONSIGNEE NUMBER		**9. IMPORTER NUMBER**
	NAME/ADDRESS		(b) (4)
10. ULTIMATE CONSIGNEE NAME		**11. IMPORTER OF RECORD NAME**	
(b) (4)		(b) (4)	
12. CARRIER CODE	**13. VOYAGE/FLIGHT/TRIP**	**14. LOCATION OF GOODS-CODE(S)/NAME(S)**	
(b) (4)	(b) (4)	(b) (4)	
15. VESSEL CODE/NAME			
16. U.S. PORT OF UNLADING	**17. MANIFEST NUMBER**	**18. G.O. NUMBER**	**19. TOTAL VALUE**
2095			(b) (4)

20. DESCRIPTION OF MERCHANDISE

PHARMACEUTICALS/THIOPENTAL

21. IT/BL/AWB CODE	22. IT/BL/AWB NO.	23. MANIFEST QUANTITY	24. H.S. NUMBER	25. COUNTRY OF ORIGIN	26. MANUFACTURER ID.
	TOTAL	(b) (4)	(b) (4)	GB	GBDREPHA176LON
M	02358486234				
H	688760418241				

27. CERTIFICATION

I hereby make application for entry/immediate delivery. I certify that the above information is accurate, the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met.

SIGNATURE OF APPLICANT
(b) (7)(C)

PHONE NO. (b) (4)

DATE 09/20/10

28. CUSTOMS USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

☐ CUSTOMS EXAMINATION REQUIRED.

☐ ENTRY REJECTED, BECAUSE:

DELIVERY AUTHORIZED: SIGNATURE DATE

DTR - AAP/REG

29. BROKER OR OTHER GOVT. AGENCY USE

RLS
9/27/10

Paperwork Reduction Act Notice: This information is needed to determine the admissibility of imports into the United States and to provide the necessary information for the examination of the cargo and to establish the liability for payment of duties and taxes. Your response is necessary.

09/20/10 17:50:54 (b) (4)

Customs Form 3461 (010189)

FDA 286

Dream Pharma Ltd.

176 Horn Lane, Acton, London, W3 6PJ
Tel: 020 8992 7000 Fax: 020 8992 7001
E-Mail: info@dreampharma.com

Invoice Details

Number: 2668INV

Date: 17-09-2010

Address:
(b) (4)

Delivery Address:
(b) (4)

VAT no:
Purchase Order:

Currency: GBP - Pounds sterling
Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description	Quantity	Price	Total
Thiopental Injection , powder for reconstitution, thiopental sodium, 500-mg vial packs of 25's Batch No: AW6022 EXP: 05/14		(b) (4)	

Statement Details

Goods Total: (b) (4)	Subtotal: (b) (4)
Discount (%): (b) (4)	VAT (World Zero) (b) (4)
Delivery (b) (4)	Previous Balance: (b) (4)
Insurance: (b) (4)	**Total:** (b) (4) GBP - Pounds sterling
	Payment Method: Prepayment Thank You

Shipping Details

Packing: one box	Gross Weight (Kg): (b) (4) Net Weight (Kg): (b) (4)
Tariff: (b) (4)	Carrier: (b) (4)
Declarations: We certify that this invoice is true and correct.	Matt Alavi, for Dream Pharma Ltd 176 Horn Lane Acton, London W3 6PJ Tel: 020-8992-7000 Fax: 020-8992-7001

DREAM PHARMA LTD

Damage, shortage or leakage must be notified in writing to ourselves within 3 days. Non-Delivery within 14 days. Goods remain the property of Dream Pharma Ltd. Until full payment has been received. Subject to our standard conditions of sale. E&OE

Company Registration Number: (b) (4) VAT No. (b) (4)
Director: M. Alavi

FDA 287

ENTRY NUMBER: 112 8992979 0 PAGE: 1
AWB/BL NBR : (b) (4) INVOICE # 09/20/2010
LINE CONSOL. WORKSHEET 05:55 PM

ITEMS MARKED 1 C/O- GB LINE VALUE- GBP
TARIFF # (b) (4)
QTY 1: KG
(b) (4)

** **

**** (b) (4)

*** END OF REPORT ***

ENTRY NUMBER: 112 8992979 0 PAGE: 1
AWB/BL NBR : (b)(4) INVOICE # 09/20/2010
SHIPPER : DREAM PHARMA LTD 05:55 PM
ITEM MARKED REFERENCE

INVOICE LINE#	ITEM MARK	TARIFF NUMBER	COUNTRY OF ORIG.	RATE OF DUTY		VALUE-GBP
1	1	(b)(4)	GB		Q:	(b)(4)

*** END OF REPORT ***

c/o mfg info

Archimedes Pharma UK Ltd
250 South Oak Way, Green Park, Reading, RG2 6UG, UK
Telephone: +44 (0)118 931 5050
Fax: +44 (0)118 931 5056
WWW: http://www.archimedespharma.com
Before you contact this company: often several companies will market medicines with the same active ingredient. Please check that this is the correct company before contacting them. Why?

Archimedes

All (b) (7)(C)

Summary of Product Characteristics last updated on the eMC: 05/05/2004

Thiopental injection

(b) (4)

1. NAME OF THE MEDICINAL PRODUCT

Thiopental Injection BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Thiopental Sodium BP 500mg

3. PHARMACEUTICAL FORM

Freeze-dried powder for solution for injection in a vial.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

1. Thiopental is used for the induction of general anaesthesia and is also used as an adjunct to provide hypnosis during balanced anaesthesia with other anaesthetic agents, including analgesics and muscle relaxants.

2. Thiopental is also used as an adjunct for control of convulsive disorders of various aetiology, including those caused by local anaesthetics.

3. Thiopental has now been used to reduce the intracranial pressure in patients with increased intracranial pressure, if controlled ventilation is provided.

4.2 Posology and method of administration

Intravenous injection.

Thiopental injection BP is administered intravenously normally as a 2.5% w/v (500mg in 20ml) solution. On occasions it may be administered as a 5% w/v solution (500mg in 10ml).

The intravenous injection preparation should be used after reconstitution of the sterile powder with Water for Injections, usually to produce a 2.5% w/v solution and this should be discarded after seven hours.

Use in anaesthesia

Normal dosage for the induction of anaesthesia is 100mg to 150mg injected over 10 to 15 seconds. If necessary a repeat dose of 100mg to 150mg may be given after one minute. No fixed dosage recommendations for the intravenous injection can be given, since the dosage will need to be carefully adjusted according to the patient's response. Factors such as age, sex, and weight of the patient should be taken into consideration. Thiopental sodium reaches effective concentrations in the brain within 30 seconds and anaesthesia is normally produced within one minute of an intravenous dose.

Adult

100mg to 150mg intravenously over 10 to 15 seconds, normally as a 2.5% w/v solution.

A repeat dose of 100mg to 150mg may be given after one minute.

The intravenous injection should be given slowly and the amounts given titrated against the patient's response to minimise the risk of respiratory depression or the possibility of overdosage. The average dose for an adult of 70kg is roughly 200mg to 300mg (8mls to 12mls of a 2.5% w/v solution) with a maximum of 500mg.

Children

2 to 7mg/kg bodyweight, intravenously over 10 to 15 seconds, normally as a 2.5% w/v solution. A repeat dose of 2 to 7mg/kg may be given after one minute. The dose is 2 to 7mg/kg based on the patient's response. The dose for children should not exceed 7mg/kg.

Elderly

Smaller adult doses are advisable.

Use in convulsive states

75mg to 125mg (3mls to 5mls of a 2.5% w/v solution) should be given as soon as possible after the convulsion begins. Further doses may be required to control convulsions following the use of a local anaesthetic. Other regimens, such as the use of intravenous or rectal diazepam, may be used to control convulsive states.

Use in neurological patients with raised intracranial pressure

Intermittent bolus injections of 1.5 to 3mg/kg of bodyweight may be given to reduce elevations of intracranial pressure if controlled ventilation is provided.

4.3 Contraindications

Thiopental is contraindicated in respiratory obstruction, acute asthma, severe shock and dystrophia myotonica. Administration of any barbiturate is contraindicated in porphyria.

Care should also be exercised with severe cardiovascular diseases, severe respiratory diseases and hypertension of various aetiology.

Patients with hypersensitivity reactions to barbiturates.

4.4 Special warnings and precautions for use

Special care is needed in administering thiopental to patients with the following conditions:- hypovolaemia, severe haemorrhage, burns, dehydration, severe anaemia, cardiovascular disease, status asthmaticus, severe liver disease, myasthenia gravis and muscular dystrophies, adrenocortical insufficiency (even when controlled by cortisone), cachexia and severe toxaemia, raised intracranial pressure, raised blood urea, raised plasma potassium, metabolic disorders e.g. thyrotoxicosis, myxoedema, diabetes.

Thiopental may precipitate acute circulatory failure in patients with cardiovascular disease, particularly constrictive pericarditis.

Thiopental can cause respiratory depression and a reduction in cardiac output.

Headache is also reported with the use of barbiturate anaesthetics.

Reduced doses are recommended in shock, dehydration, severe anaemia, hyperkalaemia, toxaemia, myxoedema or other metabolic disorders. Thiopental sodium is metabolised primarily by the liver so doses should be reduced in patients with hepatic impairment. Reduced doses are also indicated in the elderly and in

patients who have been premedicated with narcotic analgesics.

Thiopental has been shown to interact with sulphafurazole. Reduced initial doses may be required to achieve adequate anaesthesia, but repeat doses may also be necessary to maintain anaesthesia.

Increased doses may be necessary in patients who have either an habituation or addiction to alcohol or drugs of abuse. Under these circumstances it is recommended that supplementary analgesic agents are used.

Accidental intra-arterial injection of thiopental causes severe arterial spasm and an intense burning pain around the injection site. In the case of accidental intra-arterial injection of thiopental the needle should be left in-situ so that an injection of an antispasmodic, such as papaverine or prilocaine hydrochloride may be given. Anticoagulant therapy may also be started to reduce the risk of thrombosis.

Thiopental injection should be used with caution in patients with adrenocortical insufficiency or with raised intracranial pressure.

4.5 Interaction with other medicinal products and other forms of interaction

Thiopental has been shown to interact with sulphafurazole.

It should be noted that thiopental will interact with beta-blockers and calcium antagonists causing a fall in blood pressure.

The sedative properties of antipsychotics and anxiolytics may be potentiated by thiopental.

4.6 Pregnancy and lactation

Thiopental readily crosses the placental barrier and also appears in breast milk. Therefore, breast-feeding should be temporarily suspended or breast milk expressed before the induction of anaesthesia. It has been shown that thiopental can be used without adverse effects during pregnancy although the total dose should not exceed 250mg. However, when considering use of thiopental the clinician should only use the drug when the expected benefits outweigh any potential risks.

4.7 Effects on ability to drive and use machines

Post-operative vertigo, disorientation and sedation may be prolonged and out-patients given thiopental should therefore be advised not to drive or use machinery, especially within the first 24 to 36 hours.

4.8 Undesirable effects

Laryngeal spasm may occur, together with coughing or sneezing, during the induction procedure. For this reason it is not advised to use thiopental alone for peroral endoscopy.

Extravasation causes local tissue necrosis and severe pain. This can be relieved by application of an ice pack and local injection of hydrocortisone. The 5% w/v solution is hypertonic and may cause pain on injection and thrombophlebitis.

Allergic reactions, skin reactions and hypersensitivity have been rarely reported.

Bronchospasm, respiratory depression and myocardial depression or cardiac arrhythmias may occur.

4.9 Overdose

Overdosage produces acute respiratory depression, hypotension, circulatory failure and apnoea. Treatment must be artificial ventilation, lowering of the patient's head and infusion of plasma volume expanders.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Thiopental is a short-acting substituted barbiturate that is more lipid soluble than other groups of barbiturates. The drug reversibly depresses the activity of all excitable tissues. The CNS is particularly sensitive and normally a general anaesthesia can be achieved with thiopental without significant effects on peripheral tissues.

Thiopental acts through the CNS with particular activity in the mesencephalic reticular activating system. The barbiturates exert different effects on synaptic transmission, mostly those dependent on GABA. Autonomic ganglia of the peripheral nervous system are also depressed.

5.2 Pharmacokinetic properties

Following intravenous administration, unconsciousness occurs within 30 seconds and will be continued for 20 to 30 minutes after a single dose. Rapid uptake occurs to most vascular areas of the brain followed by redistribution into other tissues.

Thiopental is strongly bound to plasma protein, which impairs excretion through the kidney. The metabolites are usually inactive and are then excreted. Thiopental, therefore, whilst having a short duration of action, may have a long elimination phase.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

Solutions of thiopental injection have a pH of 10 to 11 and are strongly alkaline in order to maintain stability. Solutions are incompatible with acid, acidic salts and solutions such as pethidine, morphine and promethazine

6.3 Shelf life

48 months.

6.4 Special precautions for storage

Do not store above 25°C. Store reconstituted solution between 1°C to 8°C in an upright position and use within 7 hours. Use once following reconstitution and discard any residue.

6.5 Nature and contents of container

20ml Type III clear glass vials with 20mm bromylbutyl caoutchouc silicenised rubber closures.

Pack size: 25 vials per pack.

6.6 Special precautions for disposal and other handling

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Link Pharmaceuticals Limited, Bishops Weald House, Albion Way, Horsham, West Sussex RH12 1AH, UK

8. MARKETING AUTHORISATION NUMBER(S)

PL 12406/0014

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5 April 1999

10. DATE OF REVISION OF THE TEXT

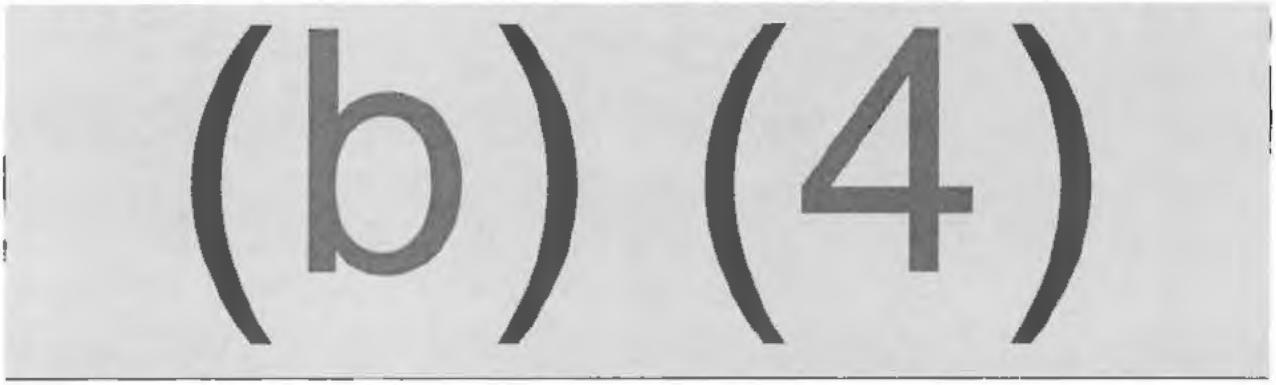
January 2003

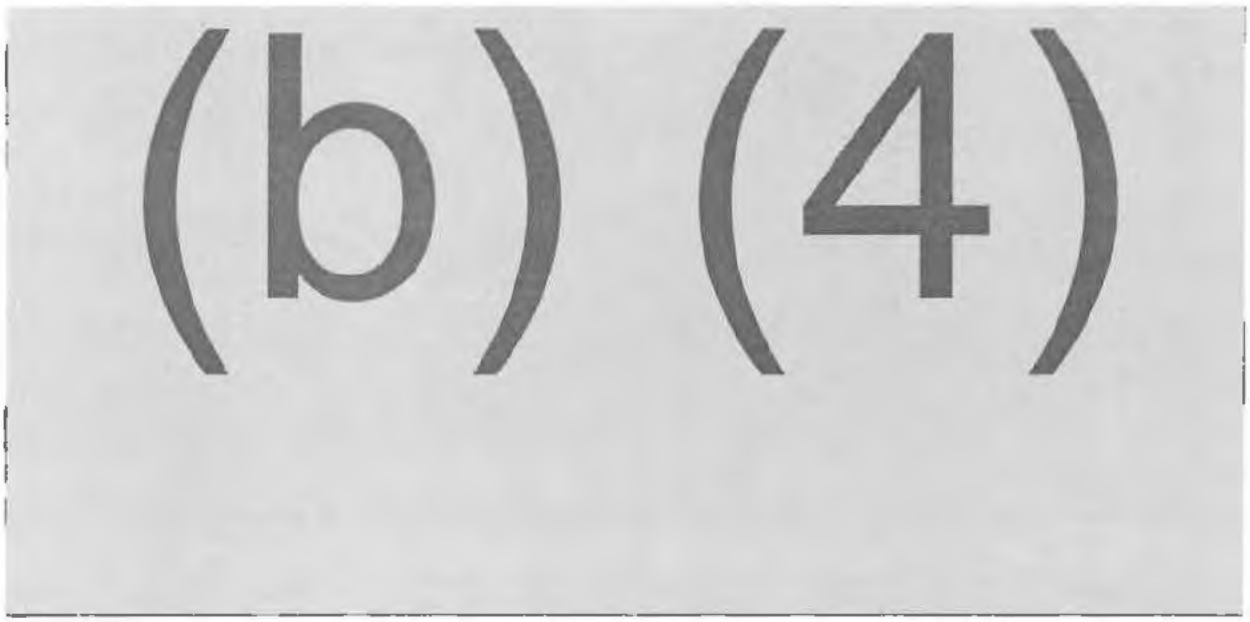
11. Legal Category

POM

(b) (4) **Manifest report**

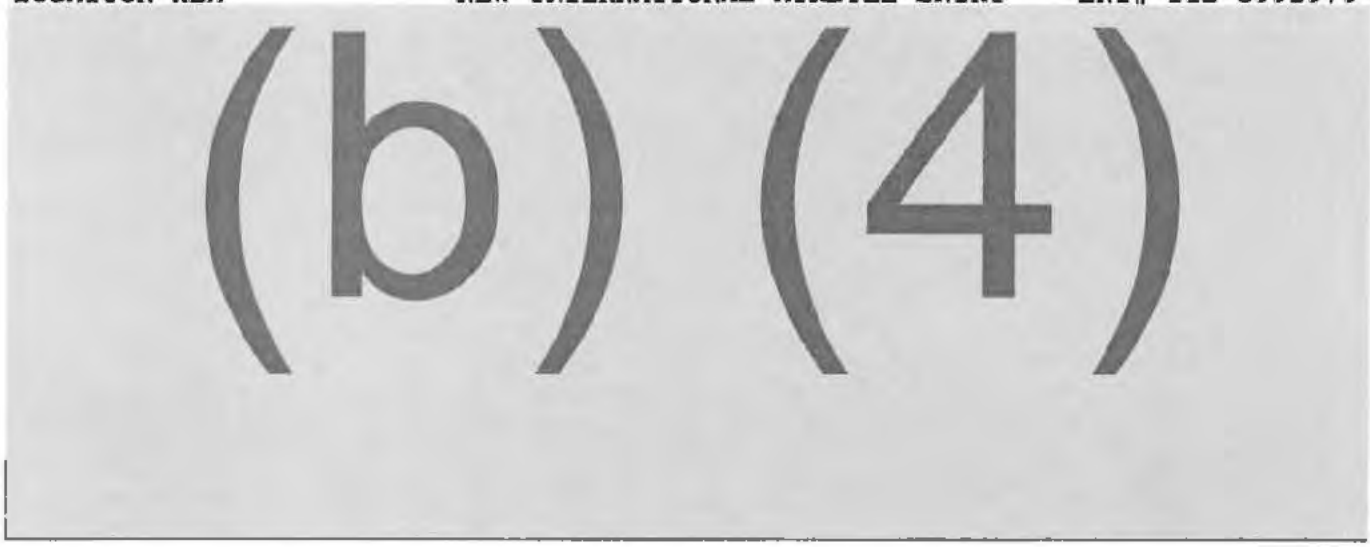
SHP DT 17-SEP-2010 SHIP# (b) (4) METER THERMAL (S RECIP# (b) (4) SOURCE CODE





FDA 294

LOCATION MEM NEW INTERNATIONAL AIRBILL ENTRY ENT# 112-8992979-0



ATTACHMENT C

AFFIDAVIT OF [redacted]

STATE OF TEXAS §
§
COUNTY OF WALKER §

Before me, the undersigned authority, personally appeared [redacted], who, being by me duly sworn, deposed as follows:

My name is [redacted]. I am over 21 years of age, of sound mind, capable of making this affidavit, and personally acquainted with the facts stated herein. I am currently employed as the [redacted] and have held that position since [redacted]. Prior to that I was the [redacted], a position I held from [redacted], and prior to that, I was the [redacted] from [redacted]. My office is located in [redacted].

[redacted] owns 113 Controlled Substance Registration Certificates from the Drug Enforcement Administration, for use at 109 facilities that provide housing and medical care to almost 148,000 offenders in the state of Texas. Each [redacted] facility has an infirmary to provide medical care and medication to the offenders housed at that location. The state of Texas spent approximately $45 million in fiscal year 2015 on pharmaceuticals for use by the offender population housed in the 109 TDCJ facilities. The pharmaceuticals include controlled substances to be used as prescribed by physicians.

"Further affiant sayeth not."

[redacted]

SWORN TO AND SUBSCRIBED BEFORE ME, the undersigned notary public, on this the 19th day of May, 2016.

[redacted]

[redacted]
NOTARY PUBLIC
STATE OF TEXAS
MY COMM. EXP. 07-23-2017

ATTACHMENT D

AFFIDAVIT OF [redacted]

STATE OF TEXAS §
§
COUNTY OF WALKER §

Before me, the undersigned authority, personally appeared [redacted] who, being by me duly sworn, deposed as follows:

My name is [redacted]. I am over 21 years of age, of sound mind, capable of making this affidavit, and personally acquainted with the facts stated herein. I am currently employed as the [redacted] and have held that position since [redacted]. Prior to that I was the [redacted], a position I held from [redacted], and prior to that, I was the [redacted]. My office is located in [redacted].

The execution protocol controlling lethal injection procedures requires strict adherence by all involved in the execution process. The protocol provides the details of the execution process, including the handling, transport, preparation, and administration of drugs.

[redacted] execution protocol currently requires the use of pentobarbital. However, in order to ensure [redacted] ability to carry out its statutory mandate, [redacted] considers alternatives to pentobarbital, including thiopental sodium, as a contingency should [redacted] find pentobarbital unavailable. If [redacted] created a new execution protocol involving thiopental sodium, the process would continue to be strictly controlled by the protocol and opportunities for discretionary use of the drug would be unavailable and prohibited.

"Further affiant sayeth not."

[redacted]

SWORN TO AND SUBSCRIBED BEFORE ME, the undersigned notary public, on this the 16th day of May, 2016.

[redacted]

[redacted]
NOTARY PUBLIC
STATE OF TEXAS
MY COMM. EXP. 07-23-2017

ATTACHMENT E

AFFIDAVIT OF [redacted]

STATE OF TEXAS §
§
COUNTY OF WALKER §

Before me, the undersigned authority, personally appeared [redacted], who, being by me duly sworn, deposed as follows:

My name is [redacted]. I am over 21 years of age, of sound mind, capable of making this affidavit, and personally acquainted with the facts stated herein. I am currently employed as the [redacted] and have held that position since [redacted]. Prior to that I was the [redacted], a position I held from [redacted], and prior to that, I was the [redacted] from [redacted]. My office is located in [redacted].

During the past ten years, [redacted] has executed 182 offenders by administering lethal injection. It is likely that [redacted] will continue to execute additional offenders through lethal injection, on a recurring and continuing basis, for the foreseeable future.

There currently are 244 offenders who have received a capital sentence in [redacted] and who are awaiting execution through lethal injection. Eight offenders are scheduled to be executed in the remainder of 2016. Based on the average number of scheduled executions in the last five years, more than 20 will receive execution dates next year and subsequent years thereafter. Unless a court intervenes, these offenders will be executed through lethal injection, as directed in their capital sentences.

Because it is likely that [redacted] will continue to execute additional offenders on a recurring and continuing basis for the foreseeable future, [redacted] needs a continuing and recurring supply of drugs to be used for lethal injection. [redacted] has previously purchased and used thiopental sodium in numerous executions. [redacted] is preparing for a contingency in which [redacted] may once again utilize thiopental sodium in executions and will do so when necessary if FDA releases its hold on the purchased thiopental sodium that is being detained by FDA. For the reasons stated in [redacted] two submissions to FDA in this matter, [redacted] has concluded that it is lawful to import the thiopental sodium entry currently being detained by FDA. Because there are currently no domestic manufacturers of that drug, [redacted] intends to continue importing thiopental sodium from the same foreign source, and with the same labeling, as the entry that FDA is currently detaining. Based on FDA's actions thus far as well as FDA's applicable import procedures, [redacted] has a reasonable expectation that when it imports future shipments of thiopental sodium from the same source and with the same labeling, FDA will take the same actions taken on the detained entry, based on the same legal analysis, unless a court intervenes.

If FDA were to refuse admission into domestic commerce of the drugs currently being detained, [redacted] currently intends to seek judicial review of that action. [redacted] has requested FDA to retain custody of the detained drugs under conditions that preserve their integrity pending

completion of any judicial review. Alternatively, if FDA refuses the entry but denies the request to retain custody, [redacted] has requested FDA to confirm that [redacted] will be given 90 days to export the drugs to the original foreign distributor. Under those circumstances, [redacted] will request the foreign distributor to hold the drugs outside the United States pending the conclusion of judicial review and (assuming a favorable court ruling) re-import the very same drugs.

"Further affiant sayeth not."

[redacted]

SWORN TO AND SUBSCRIBED BEFORE ME, the undersigned notary public, on this the 19th day of May, 2016.

[redacted]
NOTARY PUBLIC
STATE OF TEXAS
MY COMM. EXP. 07-23-2017

[redacted]

REFERENCE 9

From: Santos, Rosa L
To: [redacted]
Subject: RE: Extension Request re Entry [redacted]
Date: Thursday, April 28, 2016 4:33:00 PM

Good Afternoon [redacted];

The extension was granted until May 20, 2016.

Thanks,

Rosa Linda Santos
Compliance Officer
4040 N. Central Expressway
Suite 300
Dallas, Texas 75204
214-253-5269 Phone
214-253-5316 Fax
rosa.santos@fda.hhs.gov

From: [redacted]
Sent: Thursday, April 28, 2016 1:13 PM
To: Santos, Rosa L
Cc: [redacted]
Subject: Extension Request re Entry [redacted]

Hi Rosa Linda

The [redacted] is requesting a short extension of time, to and including May 20, 2016, to respond in writing to the tentative determination attached to your April 18, 2016 email. I would appreciate it if you would please let me know via return email if a deadline of May 20 is acceptable.

Thanks and best regards.

[redacted]

mail so that our address records can be corrected.

IRS CIRCULAR 230 DISCLOSURE: To ensure compliance with requirements imposed by the IRS, we inform you that any U.S. tax advice contained in this communication (including any attachments) is not intended or written to be used, and cannot be used, for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein. Please do not hesitate to contact me, however, if you have any questions regarding this matter.

On Monday, April 18, 2016, Santos, Rosa L <Rosa.Santos@fda.hhs.gov> wrote:
Good Morning,

Please see attached letter.

Thanks,

Rosa Linda Santos
Compliance Officer
4040 N. Central Expressway
Suite 300
Dallas, Texas 75204
214-253-5269 Phone
214-253-5316 Fax
rosa.santos@fda.hhs.gov

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[redacted]

REFERENCE 10